REMARKS

In the Claims

Claims 43, 52, 55 and 59 are amended herein as noted above. Claims 51 and 53 are cancelled herein, without prejudice. Claims 62-75 have been added. Claims 43-45, 47-49, 51, 54, 56-59, and 61 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application 2004/0092892 to Bessler. Claims 43-51, 54, and 56-61 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application 2004/0082963 to Gannoe. Claims 52-53 and 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bessler or Gannoe. Claims 52-53 stand 55 are objected to as "overly broad, indefinite, [and] unclear".

Telephonic Interview

The Applicants would like to thank Examiner Gray for extending the opportunity to Applicants' representative for the telephonic interview conducted on November 30, 2006. In the interview, the Examiner and Applicants' representative discussed the applied Bessler and Gannoe references, and the amendment proposed herein to Claim 43. Applicants' representative also indicated an intention to submit certain new dependent claims.

Rejections under § 35 U.S.C. 102(e)

According to the Examiner, Bessler discloses a method for treating obesity with the steps of providing a gastric sleeve with a proximal end, distal end, and lumen extending therethrough, transesophageally advancing the sleeve adjacent an attachment site near the gastroesophageal junction, advancing the proximal end at the attachment site to deliver food from the esophagus directly into the intestine (Office Action, p. 3). Gannoe is said to teach a method for treating obesity by providing a lengthy sleeve and support tissue anchor with a temp or permanent cuff by suture transesophageally to an attachment site near the gastroesophageal junction, with a proximal and distal ends, where the distal end can extend into the intestines or beyond (Office Action, p. 3).

While Applicants do not necessarily agree with the foregoing characterizations or the rejections, Claim 43 has been amended to for clarification purposes to recite, *inter alia*, "attaching the proximal end at the attachment site, such that the sleeve is configured to deliver food from the esophagus directly into the intestine; wherein the attaching the proximal end step comprises using at least one tissue anchor configured to have a transversely reduced

configuration for passing transmurally through the attachment site and a transversely enlarged configuration after passing transmurally through the attachment site, to engage serosal tissue to retain the sleeve." Written description support for the amendment can be found, for example, at paragraphs [0163], [0164], [0193], [0221] and Figs. 6B-D, 55-57, 75A-F, 89A-D of the disclosure, which describe numerous embodiments where tissue anchors (that may be deliverable in a delivery cannula) having a reduced configuration when passing transmurally through the attachment site and a transversely enlarged configuration after passing through the attachment site, to position a retention surface against the serosal surface of the tissue.

For example, in some embodiments, wire fasteners 130 are used as tissue anchors formed from a super elastic NiTi alloy so that the fasteners can be straightened out and passed through a delivery cannula 132, as shown in Fig. 6A. The distal tip 138 of the wire is formed so that it will assume a circular or spirally curled or curved "button" configuration 132 after it is passed through the entire wall of tissue, in other words, transmurally, as shown in Fig. 6B. The "button" shape 132 provides a surface that extends relatively transversely to the "tail" which extends transmurally, thus resisting anchor pull out. The curl of the "button" 132 can be shaped so that it protects the sharpened distal tip 138 of the wire and prevents it from damaging the stomach wall or surrounding tissues after the fastener is deployed (paragraphs [0163]-[0164]). In other embodiments, a T-pledget tissue anchor can be structured for delivery by means such as rolling and/or compressing to facilitate passage through tissue with a minimum disruption of the tissue layer. Ideally, the T-pledget would have a minimum diameter when passing through tissue (paragraph [0193]), and is designed to transversely enlarge after delivery (paragraph [0221]). Transverse enlargement can thus be accomplished in a variety of ways, such as by spring bias to expand or form a transverse surface, or by angular movement of a retention element from an axial to a transverse orientation.

Applicants submit that neither Bessler nor Gannoe teach or suggest, *inter alia*, "attaching the proximal end at the attachment site, such that the sleeve is configured to deliver food from the esophagus directly into the intestine; wherein the attaching the proximal end step comprises using at least one tissue anchor configured to have a transversely reduced configuration for passing transmurally through the attachment site and a transversely enlarged configuration after passing transmurally through the attachment site, to engage serosal tissue to retain the sleeve."

and thus respectfully request that the anticipation rejections be withdrawn. Bessler merely teaches retaining a sleeve using a non-penetrating stent member 4 against the luminal (mucosal) surface at or above the gastro-esophageal junction (paragraph [0012]). Gannoe teaches attaching a bypass conduit to a tissue plication using staples (paragraph [0034], [0035], [0042]). The inwardly directed plication is formed by bringing serosal tissue in contact with serosal tissue across a fold, to create a permanent tissue bond without bringing a transverse structure into contact with the serosal surface. See, *e.g.*, paragraph [14].

Rejections under 35 U.S.C. § 103(a)

Claims 52-53, and 55 are rejected as being unpatentable over Bessler or Gannoe. Applicants reiterate here the arguments set forth for Claims 43-51, 54, and 56-61 above and submit that neither Bessler nor Gannoe teach or suggest, *inter alia*, "attaching the proximal end at the attachment site, such that the sleeve is configured to deliver food from the esophagus directly into the intestine; wherein the attaching the proximal end step comprises using at least one tissue anchor configured to have a transversely reduced configuration for passing transmurally through the attachment site and a transversely enlarged configuration after passing transmurally through the attachment site, to engage serosal tissue to retain the sleeve." Applicants further submit that one of ordinary skill in the art would have no motivation to modify Bessler or Gannoe to produce a method as presently claimed, and that the tissue anchor claimed is not merely a matter of obvious design choice. In general, the teachings of Bessler would lead one of skill in the art in the direction of a non-penetrating anchoring system, such as a balloon expandable or self expanding stent as disclosed therein.

Nothing in Gannoe would motivate one of skill in the art to abandon the stent attachment system of Bessler and instead attach a gastric bypass sleeve in the vicinity of the gastroesophageal junction using a penetrating anchor with a transverse surface against the serosa. As seen in Figures 5B through 5E, Gannoe teaches forming a circumferential plication for the purpose of creating a stoma, or narrowing, at the base of the esophagus. In the illustrated plication, both ends of a suture or staple extend through the mucosa layer of the stomach. The pinching of the wall of the stomach brings serosa into contact with itself across the fold, which is known to promote serosa to serosa tissue healing, thereby making the plication permanent. For

that reason, Gannoe discloses that bioabsorbable fixation elements may be utilized (paragraph 14):

> Any of the fastening devices described herein may employ, e.g., bioabsorbable or biofragmentable staples or fixation element. Such fastening devices would typically dissolve or otherwise degrade leaving only the fixation region once the desired tissue healing has occurred. The remaining healed tissue, now a tissue "ring" (TR), would be sufficiently adhered or healed together to maintain the integrity of the pouch and stoma.

Gannoe also discloses the use of a pleat or plication as enhancing the longevity of the treatment. See, for example, paragraph 13:

> The devices and procedures of the present invention would allow the operator to reliably acquire and secure the necessary types of tissue, such as the muscularis, in creating the circumferential or curved tissue plication desirable to ensure a lasting clinical result.

See also paragraph 33:

> The amount of tissue 111 acquired can vary, but the amount drawn is preferably sufficient enough to result in healing of the fastened sections, thereby creating a tissue ring (TR) around the circumference of the fastened tissue.

Thus, Gannoe clearly suggests the formation of a serosa to serosa plication, to permit healing of the plication to create a permanent restriction in the flow path of the esophagus. Gannoe also discloses attaching an optional bypass conduit 113 from the pouch into the intestine. According to Gannoe at paragraph 35 (emphasis added):

> Such a bypass conduit 113 .... may be secured to the newly created tissue ring (TR) or stoma (ST) endoscopically using a clip or stent like structure at the anchored end to produce an interference fit within the stoma.

No where does Gannoe disclose the concept of attaching a bypass sleeve in the vicinity of the gastroesophageal junction using a tissue anchor configured to have a reduced configuration for passing transmurally through the attachment site and a transversely oriented configuration after passing transmurally through the attachment site. To the contrary, Gannoe teaches the need for what Gannoe apparently perceives to be a more robust attachment configuration, and simultaneous restriction, in which a circumferential plication is formed to enable serosa to serosa healing, and enable a large "bite" of muscularis within the plication.

Applicants respectfully submit that the Examiner has failed to establish a *prima facia* case of obviousness with respect to any of the claims of the present invention. In order to establish a *prima facia* case of obviousness, the Examiner must show: i) Some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, ii) a reasonable expectation of success, and iii) the prior art reference or references combined teach or suggest all of the claimed limitations. See MPEP §2142.

Applicants respectfully submit that one of skill in the art would have absolutely no motivation to add transmural attachment anchors which are movable from a reduced cross section to an enlarged cross section to the disclose of Bessler. To the contrary, Bessler teaches a nonpuncturing attachment system, in the form of a self expandable or balloon expandable stent.

Nor would one of skill in art be motivated to modify the teachings of Gannoe in a manner that would produce Applicants' present claimed invention. Gannoe teaches a mucosal to mucosal puncture of a plication, for the purpose of both reducing the diameter of the opening at the base of the esophagus and permit serosa to serosa healing to enable a lasting clinical result. This disclosure would not motivate one to eliminate the plication which is contained in every embodiment disclosed in Gannoe, and instead use a simple transmural attachment anchor.

Applicants further respectfully submit that the modifications necessary to both Bessler and Gannoe to produce Applicants' claimed invention are far more than the mere interchangeability of known materials, such that the Examiner's reference to *In re: Leshin* does not appear applicable in the present case. Gannoe does not merely teach the use of staples or sutures in some broad fashion such that the substitution of T-tags might have been an obvious substitution. Rather, Gannoe discloses the use of staples or sutures in a specific context of forming a circumferential plication to create a stoma from which a bypass conduit may be hung. Within the plication, there is essentially no serosal surface left due to the healing response, so placing a T-tag or other structure against the serosal surface in this context is not a cognizable concept.

In view of the foregoing, Applicants respectfully request that the outstanding obviousness rejections be withdrawn.

"T-tag" objections

The Examiner objected to Claims 52-53 and 55, finding that the recitation of a "T-tag" is overly broad, indefinite, unclear, and fails to particularly point out what applicant considers his invention or any corresponding structure. Applicants disagree, and submit that a "T-tag" is both understood in the art, and is clearly defined in the disclosure.

For example, paragraph [0166], states in part that a "T-tag is basically a cross member or "T" that is attached to an elongated member or tail at or near the mid-point of the T." As recited in paragraph [227], "the purpose of the T in a T-fastener is to distribute and resist the forces that could act to pull it through the tissue, in this case the gastric wall".

In general, the T-tag is one way of providing a serosal surface footprint which resists retraction through the stomach wall. The anchor passes transmurally from inside the tissue wall to outside the wall in a reduced cross-sectional configuration (*e.g.* by orienting the cross bar on the T into parallel with the axis of penetration) and enlarges (*e.g.* by inclining the cross bar on the T into parallel with the serosal surface) following deployment. As recited in paragraph [0166], "T-tag fasteners are generally configured to flex at the juncture of the T and tail to allow delivery along the axis of the T through a minimal puncture diameter."

Applicants respectfully request that this objection be withdrawn.

NEW CLAIMS

New Claims 62 through 75 recite features which are believed to be patentably distinct from the art of record. Written description support for the everting step in Claims 62 and 67 may be found, for example, in paragraph [452]. The step of advancing an introducer through the patient's pylorus recited in Claims 63 and 68 is disclosed, for example, in paragraph [453]. The step of everting the bypass sleeve from the introducer after the introducer has been advanced through the pylorus, recited in new claims 64 and 69, is disclosed in paragraph [453]. A method of implanting a bypass sleeve using purely a peroral approach, as claimed in Claims 65 and 70, is disclosed in paragraph [454]. The method of gastric bypass sleeve implantation with laparoscopic assistance, as recited in Claims 66 and 71, is disclosed, for example, in paragraph [454]. The method of achieving a transverse enlargement of the tissue anchor by expansion is disclosed in paragraph [221]. The method of achieving a transversely enlarged configuration of the tissue anchor by flexing a portion of the tissue anchor is disclosed in paragraph [166]. The method step of visualizing passage of ingested radiopaque material through the sleeve as recited in Claim 74 is disclosed in paragraph [259]. The step of applying antegrade tension on the sleeve, such as by modifying the distal end of the sleeve to cooperate with peristaltic motion, is disclosed, for example, in paragraph [302].

CONCLUSION

In view of the foregoing, Applicant respectfully submits that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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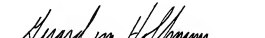
By: 
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